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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,844	07/29/2005	Richard Belanger	6013-106US	7204

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,844	BELANGER ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-20* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and remarks filed 3/17/08 are acknowledged.

Claims 7-14 have been cancelled. New claims 15-20 have been entered.

Election/Restrictions

Applicant's election of I, claims 7-10, in the reply filed on 8/17/07 is acknowledged. New claims 15 and 16 correspond to the originally elected product claims.

Newly submitted claims 17-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New claims 17 and 18 are drawn to the use of the compound and correspond to restriction group II. Claim 19 is drawn to a method for preparing the claimed compounds and corresponds to restriction group III. New claim 20 is drawn to a method of treating microbial infection with the claimed compound. This claim was not originally presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 15 and 16 are under examination.

Specification/Drawings

Applicant has apparently filed a specification and drawings to replace the originally filed documents, entered on 1/13/05. It is assumed that Applicant is filing a substitute specification and drawings. Even if Application was not intending to file a substitute, the filing of an entirely new specification and drawings would require the proper submission of a substitute specification and drawings. It is noted that the Examiner did not require the filing of a substitute specification or drawings.

It is assumed that Applicant is filing a substitute specification and drawings. The substitute specification filed 3/17/08 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: the statement as to a lack of new matter under 37 CFR 1.125(b) is missing. Furthermore, Applicant has not supplied a marked-up copy of the substitute specification has not been supplied in addition to the clean copy.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Claim Rejections - 35 USC § 112

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an antimicrobial compound obtainable from *Pseudozyma flocculosa* in a culture medium, wherein the physical characteristics of said compound are recited by spectral data including FAB mass spectroscopy, ^{1}HNMR and ^{13}CNMR.

The specification discloses the compound flocculosin, depicted in Figure 1, which corresponds to the claimed spectral data. The compound flocculosin meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 15 and 16 are directed to encompass any antimicrobial compound obtainable by culturing *Pseudozyma flocculosa*. The "open" transitional language of the claims ("comprising") and the supporting disclosure by the specification (page 4, lines 10-15) embraces the scope of the derivatives and analogs of flocculosin which only correspond in some undefined way to specifically the instantly disclosed compound flocculosin. None of these derivatives or analogs meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of

possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, flocculosin, the only structurally defined compound described by the claimed spectral data, but not the full breadth of the claims meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded

that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claims 15 and 116 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound flocculosin as defined by the recited spectral data and that is obtained by culturing *Pseudozyma flocculosa* (ATCC 64874), does not reasonably provide enablement for the compound flocculosin as defined by the recited spectral data that is obtainable by culturing any possible strain of *Pseudozyma flocculosa*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims are drawn to an antimicrobial compound obtainable from *Pseudozyma flocculosa* on a culture medium, wherein the physical characteristics of said compound are recited by spectral data including FAB mass spectroscopy, ^{1}HNMR and ^{13}CNMR.

The specification discloses that flocculosin, as defined by the claimed spectral data, is obtained from one particular strain *Pseudozyma flocculosa* (ATCC 64874). It is also disclosed that prior art references have not shown the existence of flocculosin and the use or any operable aspects of the compound (p. 6, lines 1-2). Therefore, flocculosin is a novel compound and the method of its production is described only in the instant specification. That is, the compound is obtained from one known strain, *Pseudozyma flocculosa* (ATCC 64874).

The scope of the instant claims ("obtainable from *Pseudozyma flocculosa*") embraces the production and isolation of the claimed compound from any possible strain of *Pseudozyma flocculosa* as well as from any other microbial source.

The specification does not disclose if one skilled in the art can utilize any strain of *Pseudozyma flocculosa* or any other microorganism to produce the compound of claims 15 and 16 with a reasonable expectation of results. It is noted that ATCC discloses that ATCC 64874 is identified as *Stephanoascus flocculosus* Traquair et al., teleomorph and that there are no further entries for *Pseudozyma flocculosa*. It appears that the ability of the disclosed strain to produce the compound of claim 15 is rare and an individual characteristic of said strain. Hence, one skilled in the art would be unable to pick a strain from said specie and expect it to possess the same set of properties. If the method of claims 15 and 16 are not generally applicable to any strain of the disclosed specie, then the desired production of flocculosin in all possible strains of the specie *Pseudozyma flocculosa* would be considered individually. This would be considered undue experimentation.

There is no reliable method that predicts which strains from the specie *Pseudozyma flocculosa* have the desired ability to produce flocculosin as described in the specification. The specification does not teach how one of ordinary skill in the art could decide *a priori* which sources will provide a microorganism with the desired characteristics. The limited disclosure cannot be extrapolated by the skilled artisan to predict which strains from *Pseudozyma flocculosa* are capable of producing flocculosin. It would require one of ordinary skill in the art undue experimentation to determine what

strains of *Pseudozyma flocculosa can produce flocculosin* according to the directions of the instant disclosure. Thus, claims 15 and 16 are not commensurate in scope with the enabling disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651